

ORAL ARGUMENT NOT YET SCHEDULED**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

AMERICAN WATER WORKS
ASSOCIATION and ASSOCIATION
OF METROPOLITAN WATER
AGENCIES,

Petitioners,

v.

UNITED STATES
ENVIRONMENTAL PROTECTION
AGENCY and LEE M. ZELDIN, in his
official capacity as EPA Administrator,

Respondents.

No. 24-1188 (consolidated with
Nos. 24-1191, 24-1192)

**RESPONSE OF PETITIONERS AMERICAN WATER WORKS
ASSOCIATION AND ASSOCIATION OF METROPOLITAN WATER
AGENCIES IN SUPPORT OF RESPONDENTS' MOTION FOR PARTIAL
VACATUR**

(Names and addresses of counsel appear on next page.)

Dated: September 26, 2025

Corinne V. Snow
VINSON & ELKINS LLP
2200 Pennsylvania Avenue NW
Suite 500 West
Washington DC 20037
csnow@velaw.com
Phone: (202) 639-6622
Fax: (917) 879-8998

*Counsel for Petitioners American Water
Works Association and Association of
Metropolitan Water Agencies
(Case No. 24-1188)*

TABLE OF CONTENTS

Table of Authorities	ii
Introduction	1
Background	2
A. Legal Background	2
B. Factual Background.....	7
C. Procedural Background	10
Argument.....	12
I. EPA correctly recognizes that it unlawfully proposed regulations for the Index PFAS before issuing Determinations to Regulate for those PFAS.	12
II. EPA’s error harmed Water Associations.	13
III. The Court can and should vacate those portions of the Rule that EPA requests be vacated.	19
Conclusion	22
Certificate of Compliance	24
Certificate of Service	25

TABLE OF AUTHORITIES

Cases:	<u>Page(s)</u>
<i>Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm’n</i> , 988 F.2d 146 (D.C. Cir. 1993)	26, 27
<i>Am. Bankers Ass’n v. Nat’l Credit Union Admin.</i> , 934 F.3d 649 (D.C. Cir. 2019)	27
<i>Bldg. Indus. Legal Def. Found. v. Norton</i> , 231 F. Supp. 2d 100 (D.D.C. 2002)	15
<i>Chamber of Commerce of U.S. v. SEC</i> , 443 F.3d 890 (D.C. Cir. 2006)	18, 23
<i>City of Waukesha v. EPA</i> , 320 F.3d 228 (D.C. Cir. 2003)	17, 19, 21
<i>Daimler Trucks N. Am. LLC v. EPA</i> , 737 F.3d 95 (D.C. Cir. 2013)	24
<i>Ethyl Corp. v. Browner</i> , 989 F.2d 522 (D.C. Cir. 1993)	16
<i>Freytag v. Comm’r</i> , 501 U.S. 868 (1991)	16
<i>Heartland Reg’l Med. Ctr. v. Sebelius</i> , 566 F.3d 193 (D.C. Cir. 2009)	25
<i>In re Barr Laboratories, Inc.</i> , 930 F.2d 72 (D.C. Cir. 1991)	17
<i>Jicarilla Apache Nation v. U.S. Dep’t of Interior</i> , 613 F.3d 1112 (D.C. Cir. 2010)	19
<i>Loper Bright Enters. v. Raimondo</i> , 144 S. Ct. 2244 (2024)	15
<i>Mack Trucks, Inc. v. EPA</i> , 682 F.3d 87 (D.C. Cir. 2012)	19

Cases—Continued:**Page(s)**

<i>Nat. Res. Def. Council v. Regan</i> , 67 F.4th 397 (D.C. Cir. 2023)	8
<i>Nat. Res. Def. Council v. Wheeler</i> , 955 F.3d 68 (D.C. Cir. 2020)	24, 25, 27
<i>Safer Chems., Healthy Fams. v. EPA</i> , 791 F. App'x 653 (9th Cir. 2019)	15
<i>Shell Oil Co v. EPA</i> , 950 F.2d 741 (D.C. Cir. 1991)	18, 24
<i>Shinseki v. Sanders</i> , 556 U.S. 396 (2009)	17, 19
<i>Sprint Corp. v. FCC</i> , 315 F.3d 369 (D.C. Cir. 2003)	19
<i>Standing Rock Sioux Tribe v. U.S. Army Corps of Eng'rs</i> , 985 F.3d 1032 (D.C. Cir. 2021)	25
<i>Sugar Cane Growers Coop. v. Veneman</i> , 289 F.3d 89 (D.C. Cir. 2002)	18, 20
<i>United States v. Pryce</i> , 938 F.2d 1343 (D.C. Cir. 1991)	17
<i>WildEarth Guardians v. U.S. Bureau of Land Mgmt.</i> , 870 F.3d 1222 (10th Cir. 2017)	16
<i>Window Covering Mfrs. Ass'n v. CPSC</i> , 82 F.4th 1273 (D.C. Cir. 2023)	23

Statutes:

42 U.S.C. § 300g-1(a)(3)	9
42 U.S.C. § 300g-1(b)(1)(A)	5, 6
42 U.S.C. § 300g-1(b)(1)(B)(i)	3

Statutes—Continued:**Page(s)**

42 U.S.C. § 300g-1(b)(1)(B)(i)(I)	3
42 U.S.C. § 300g-1(b)(1)(B)(ii)(I)	4, 5
42 U.S.C. § 300g-1(b)(1)(B)(ii)(II)	5
42 U.S.C. § 300g-1(b)(1)(E)	6, 7, 9
42 U.S.C. § 300g-1(b)(3)(C)(i)	6, 21
42 U.S.C. § 300g-1(b)(4)(A)	6
42 U.S.C. § 300g-1(b)(7)(A)	6
42 U.S.C. § 300g-1(b)(9)	8
42 U.S.C. § 300j-4(g)(1)	4
42 U.S.C. § 300j-4(g)(5)	4
42 U.S.C. § 300j-4(g)(7)(A)	4
42 U.S.C. § 300j-4(g)(7)(B)	4
America’s Water Infrastructure Act, Pub. L. No. 115-270, § 2021, 132 Stat. 3765 (2018)	4

Regulations

40 C.F.R. § 141.35	3
40 C.F.R. § 141.40(a)	3

Administrative Materials:

74 Fed. Reg. 51,850 (Oct. 8, 2009)	7
77 Fed. Reg. 26,072 (May 2, 2012)	8
81 Fed. Reg. 81,099 (Nov. 17, 2016)	7

Administrative Materials—Continued:**Page(s)**

85 Fed. Reg. 14,098 (Mar. 10, 2020).....	7
86 Fed. Reg. 12,272 (Mar. 3, 2021).....	7
86 Fed. Reg. 73,131 (Dec. 27, 2021).....	8
88 Fed. Reg. 18,638 (Mar. 29, 2023).....	8, 16
89 Fed. Reg. 32,532 (Apr. 26, 2024)	1, 9, 10, 16

Other Authorities:

Comments of American Water Works Association (May 30, 2023), Doc. ID EPA-HQ-OW-2022-0114-1759	17, 18
Comments of Association of Metropolitan Water Agencies (May 30, 2023), Doc. ID EPA-HQ-OW-2022-0114-1738	18
EPA, <i>Discuss Potential Approaches to the Sixth Unregulated Contaminant Monitoring Rule (UCMR 6)</i> (2024).....	6
H.R. Rep. No. 104-632, at 9-10 (1996)	3
Press Release, EPA, EPA Announces It Will Keep Maximum Contaminant Levels for PFOA, PFOS (May 14, 2025).....	11, 21
Resp'ts' Mot. for Partial Voluntary Remand, <i>Safer Chems., Healthy Fams. v. EPA</i> , No. 17-72260 (Aug. 6, 2018).....	13
S. Rep. No. 104-169 (1995)	3

Petitioners American Water Works Association (“AWWA”) and Association of Metropolitan Water Agencies (“AMWA”) (together, “Water Associations”) file this response in support of Respondents’ Motion for Partial Vacatur. *See* Respondents’ Motion for Partial Vacatur, Doc. No. 2134523 (Sept. 11, 2025) (“EPA Mot.”). Water Associations urge the Court to grant the motion.

INTRODUCTION

Water Associations filed this challenge, in part, because Respondent U.S. Environmental Protection Agency (“EPA” or “the Agency”) followed an unlawful process for promulgating determinations to regulate and regulations for four contaminants—(1) perfluorobutane sulfonic acid (“PFBS”), (2) perfluorohexane sulfonic acid (“PFHxS”), (3) perfluorononanoic acid (“PFNA”), and (4) hexafluoropropylene oxide dimer acid (“HFPO-DA”) (collectively, the “Index PFAS”)—and their mixtures pursuant to the Safe Drinking Water Act (the “Act”). Water Associations devoted a significant portion of their already-filed opening brief detailing the myriad legal flaws with the approach used by EPA.

Respondents now rightly move for partial vacatur of the EPA action challenged in these consolidated cases: “PFAS National Primary Drinking Water Regulation,” 89 Fed. Reg. 32,532 (Apr. 26, 2024) (“Rule”). *See* EPA Mot. 1-2. Specifically, and as explained in greater detail below and in EPA’s motion, the Agency seeks vacatur of the portions of the Rule pertaining to the Index PFAS.

Vacatur of those portions of the Rule—to allow EPA to more effectively conduct a reconsideration proceeding—is the only responsible and appropriate path forward. The Agency has admitted legal error with respect to those portions of the Rule, and its specific error, i.e., failure to adhere to statutorily required notice-and-comment procedures under the Act, warrants vacatur. EPA, moreover, has withdrawn and waived any harmless-error defense. Even if it had not, the harm is patent—EPA moved forward with regulation of the Index PFAS using data and information that interested parties (including Water Associations) had no opportunity to review and comment upon, as was required under the Act. Finally, vacatur is especially appropriate in this situation, where EPA has admitted a significant procedural error and evinces no intention of curing that error while keeping the substantive action in place. Even applying an *Allied-Signal* analysis, vacatur of the portions of the Rule that EPA seeks vacated would pose no disruptive consequences because the Rule’s first compliance deadlines are more than a year away and no currently effective public health or environmental protections would be disrupted by the partial vacatur.

BACKGROUND

A. Legal Background

The Safe Drinking Water Act requires EPA to undertake a multi-step, sequential process for regulating previously unregulated contaminants occurring in

drinking water.¹ *First*, EPA must publish, every five years, a draft Contaminant Candidate List of unregulated contaminants that are “known or anticipated to occur in public water system” and that “may require regulation.” 42 U.S.C. § 300g-1(b)(1)(B)(i). *Second*, after a notice-and-comment period, EPA finalizes the Contaminant Candidate List. *Id.* § 300g-1(b)(1)(B)(i)(I). The contaminants included on the final list are subject to reporting requirements under the Unregulated Contaminant Monitoring Rule (“UCMR”). *See* 40 C.F.R. §§ 141.35, 141.40(a). The UCMR program generates a publicly available contaminant occurrence dataset, gathered from all “public water systems that serve a population of more than 10,000,” as well as “from a representative sampling of public water systems that serve a population of 10,000 or fewer.” 42 U.S.C. § 300j-4(g)(1), (5), (7)(A)-(B); *see* America’s Water Infrastructure Act, Pub. L. No. 115-270, § 2021, 132 Stat. 3765, 3861 (2018) (expanding UCMR to capture a census of public water systems serving between 3,300 and 10,000 persons and a sample of system serving fewer than 3,300 systems, subject to availability of appropriations).

¹ The current regulatory process is the product of Congressional dissatisfaction with EPA’s implementation of the Act as it existed prior to significant amendment in 1996. The previous approach resulted in “arbitrary Federal law imposing burdens on consumers and the taxpayers ... with no rational relationship to the public benefits that might be realized” because some regulated contaminants “occur so infrequently in public water systems” that the costs of regulation “far outweigh any health benefit that could be realized.” S. Rep. No. 104-169, at 12-13 (1995); *accord* H.R. Rep. No. 104-632, at 9-10 (1996).

Third, every five years, EPA must determine whether to regulate at least five contaminants on the Contaminant Candidate List. *See* 42 U.S.C. § 300g-1(b)(1)(B)(ii)(I). When EPA wishes to regulate a contaminant, the Act requires that the Agency initially publish a “notice of the preliminary determination” to regulate (a “Preliminary Determination”) and provide an “opportunity for public comment.” *Id.*

Fourth, following issuance of the Preliminary Determination and a period for public comment, EPA must issue a “determination to regulate” (a “Determination to Regulate”), assuming that the three statutory criteria for regulation are met:

(i) the contaminant may have an adverse effect on the health of persons;

(ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

(iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

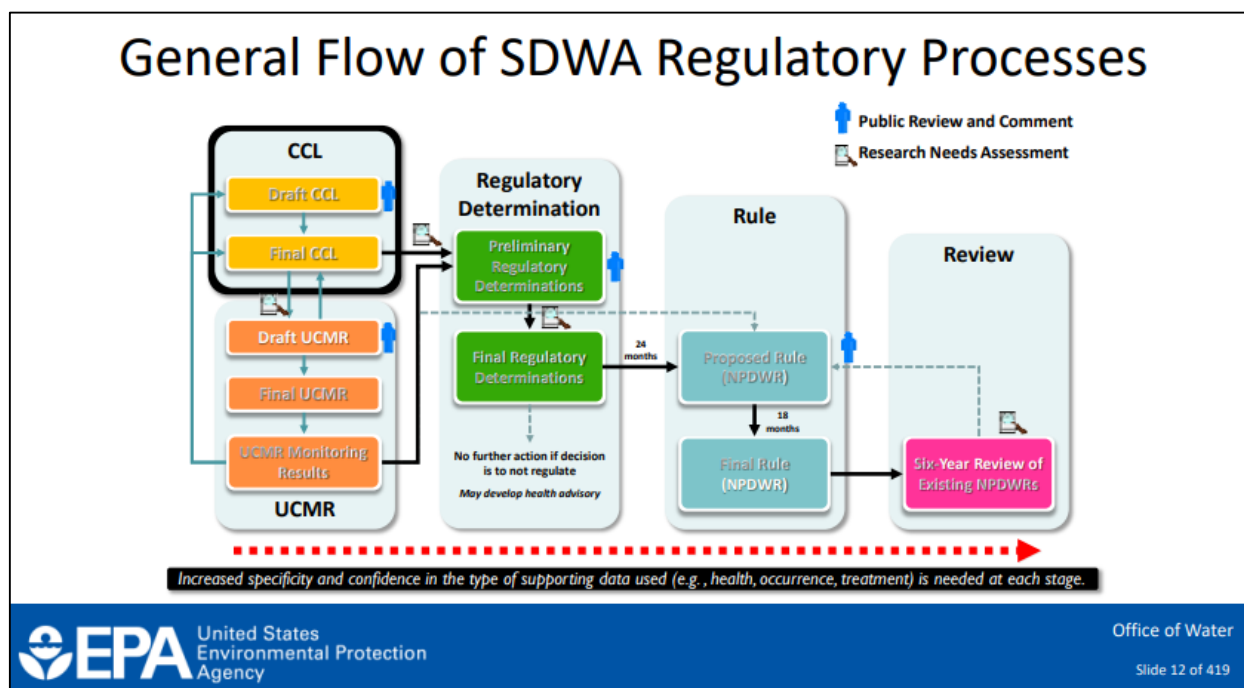
Id. § 300g-1(b)(1)(B)(ii)(II); *id.* § 300g-1(b)(1)(A)(i)-(iii) (three criteria). The Determination to Regulate must be based on “the best available public health information,” including occurrence data gathered by the UCMR program. *Id.* § 300g-1(b)(1)(B)(ii)(II).

Fifth, and assuming EPA issues a Determination to Regulate, the Agency shall propose a maximum contaminant level goal (“Goal”) for that contaminant. *Id.* § 300g-1(b)(1)(A), (E). Goals themselves are non-enforceable and simply identify the level of contaminant at which point “no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.” *Id.* § 300g-1(b)(4)(A). Accordingly, EPA must also propose a “national primary drinking water regulation.” *Id.* § 300g-1(b)(1)(E). The regulation often takes the form of a legally enforceable “maximum contaminant level” (“Level”). *Id.*² EPA is required to propose the Goal and Level for a contaminant “not later than 24 months after” the Determination to Regulate is issued, although it may publish the proposed Goal and Level concurrent with the issuance of the Determination to Regulate. *Id.* When proposing a Level, the Agency must also “publish, seek public comment on, and use” a Health Risk Reduction and Cost Analysis for the proposed Level and each alternative Level under consideration. *Id.* § 300g-1(b)(3)(C)(i).

Sixth, and finally, EPA must publish the final Goal and Level “within 18 months” of the proposed versions. *Id.* § 300g-1(b)(1)(E).

² The alternative is a “treatment technique,” *see* 42 U.S.C. § 300g-1(b)(7)(A), which is not at issue in this case.

EPA, as recently as 2024, has explained the standard-setting process under the Act in similar terms—multiple, sequential steps with several, distinct points for public notice and comment:



EPA, *Discuss Potential Approaches to the Sixth Unregulated Contaminant Monitoring Rule (UCMR 6)* at 12 (2024), <https://perma.cc/L6VH-HWWL>.

EPA’s vigilant adherence to the Act’s required procedures is essential for at least two key reasons. For one, the Act contains an anti-backsliding provision applicable to Levels promulgated pursuant to the statute: “[E]ach revision [of a national primary drinking water regulation] shall maintain, or provide for greater, protection of the health of persons.” 42 U.S.C. § 300g-1(b)(9). This means the Agency is restricted in its ability to revisit Levels once they are promulgated—akin to a one-way regulatory ratchet. For another, this Court recently held that once EPA

issues a valid Determination to Regulate, it may not withdraw it. *See Nat. Res. Def. Council v. Regan*, 67 F.4th 397, 401, 402 (D.C. Cir. 2023). The practical effect is that a valid Determination to Regulate creates a point of no return for the Agency, increasing the importance of having all potentially relevant information and stakeholder engagement before moving forward.

B. Factual Background

In 2020, EPA kicked off the underlying administrative process for this matter. EPA published Preliminary Determinations for perfluorooctanoic acid (“PFOA”) and perfluorooctane sulfonic acid (“PFOS”), two contaminants within the larger category of synthetic compounds called per- and polyfluoroalkyl substances (“PFAS”). *See* 85 Fed. Reg. 14,098 (Mar. 10, 2020).³ After collecting public comments, EPA published the Final Determinations for PFOA and PFOS in March 2021. *See* 86 Fed. Reg. 12,272 (Mar. 3, 2021). That action triggered the 24-month deadline for the Agency to propose Goals and Levels for PFOA and PFOS. *See* 42 U.S.C. § 300g-1(a)(3), (b)(1)(E). Later that year, EPA published UCMR 5 in order to collect nationally representative occurrence data from public water systems for

³ EPA had previously included PFOA and PFOS in its third and fourth Contaminant Candidate Lists. *See* 74 Fed. Reg. 51,850, 51,852 (Oct. 8, 2009); 81 Fed. Reg. 81,099, 81,104, 81,107 (Nov. 17, 2016).

PFOA, PFOS, and the four Index PFAS identified above—PFBS, PFHxS, PFNA, and HFPO-DA. *See* 86 Fed. Reg. 73,131 (Dec. 27, 2021).⁴

In March 2023, EPA proposed the collection of agency actions that are the subject of this petition proceeding. *See* 88 Fed. Reg. 18,638 (Mar. 29, 2023). The proposal included the following items:

- For each of PFOA and PFOS, Goals and Levels at zero and 4.0 parts per trillion (“ppt”), respectively;
- Preliminary Determinations for each of the Index PFAS as individual contaminants;
- A Preliminary Determination for mixtures of two or more of the Index PFAS; and
- A Goal and Level for mixtures of two or more of the Index PFAS, based on a so-called “hazard index” value of 1.0 (unitless).

Id. at 18,666-70. As described by EPA at the time, the “hazard index” is “the sum of [hazard quotients]” for a mixture of substances. A “hazard quotient,” in turn, was explained as “the ratio of potential exposure to a substance and the level at which no health effects are expected.” *Id.* at 18,668. Put differently, the hazard index purports

⁴ UCMR 5 was the first rule to include all six PFAS at issue in this case. UCMR 3 did not include HFPO-DA. *See* 77 Fed. Reg. 26,072, 26,075-76 (May 2, 2012). UCMR 5, moreover, aimed to collect more nationally representative data than UCMR 3 by gathering data from more than twice as many water systems and doing so at lower reporting thresholds. *Compare id.* at 26,090, 26,098-100 (Exhibit 9 and Table 1), *with* 86 Fed. Reg. at 73,148, 73,155-56 (Exhibit 6 and Table 1). At present, UCMR 5 is scheduled to continue to collect data through the end of this calendar year.

to identify when a particular substance may be harmful to human health insofar as it appears alongside other substances in the index. As Water Associations (and Petitioners in No. 24-1191 and 24-1192) explained in their opening briefs, EPA's use of a hazard index as a legally enforceable regulatory standard in this context was novel, unlawful, and unsupported by substantial evidence. *See* Doc. Nos. 2078734, at 33-40 (Oct. 7, 2024) (Water Associations' opening brief); 2078731, at 38-44 (Oct. 7, 2024) (opening brief of Petitioners in Nos. 24-1191 and 24-1192).

In April 2024, EPA issued the Rule that Petitioners have challenged. *See* 89 Fed. Reg. 32,532. For PFOA and PFOS, EPA finalized Goals of zero and Levels of 4.0 ppt—by far the costliest Level that EPA considered. *See id.* at 32,535, 32,710-12. EPA, moreover, issued Determinations to Regulate for PFHxS, PFNA, and HFPO-DA as individual contaminants. *Id.* at 32,535.⁵ For each of those three, individually, EPA finalized Goals and Levels of 10 ppt. *Id.* EPA also issued a Determination to Regulate mixtures of two or more Index PFAS, as well as promulgated a Goal and Level, each based on a hazard index value of 1 (unitless). *Id.* Finally, the Agency finalized monitoring, reporting, and public notification requirements, which will require public water systems to monitor for all six PFAS

⁵ EPA deferred making a determination on whether to regulate PFBS on an individual basis. 89 Fed. Reg. at 32,535.

in perpetuity, even if none of the substances has ever been detected in a system's source water. *Id.*

C. Procedural Background

Petitioners timely filed their petitions for review of the Rule. *See* Doc. Nos. 2058535 (Water Associations, No. 24-1188); 2058848 (No. 24-1191); 2059361 (No. 24-1192). Petitioners filed their opening briefs on October 7, 2024. *See* Doc. Nos. 2078734 (Water Associations); 2078731 (Petitioners in Nos. 24-1191 and 24-1192). EPA filed its answering brief on December 23, 2024, *see* Doc. No. 2091318, followed by the Respondent-Intervenors on January 17, 2025, *see* Doc. No. 2094834.

Following a change in Presidential administration, EPA moved on February 7, 2025, to place this matter into abeyance in order to allow the incoming Administration to review the Rule. *See* Doc. No. 2099439; EPA Mot. at 8; *see also* Doc. No. 2099658 (Feb. 7, 2025) (Clerk's Order granting motion for abeyance).⁶ In May 2025, EPA announced its intention to "keep" the presently existing Goals and Levels for PFOA and PFOS, "extend compliance deadlines for PFOA and PFOS,"

⁶ This case remained in abeyance until July 22, 2025. *See* Doc. Nos. 2110289 (Apr. 10, 2025) (Clerk's Order continuing abeyance); 2115832 (May 14, 2025) (same); 2119400 (June 5, 2025) (same); 2126542 (July 21, 2025) (motion to remove case from abeyance); 2126755 (July 22, 2025) (Clerk's Order granting removal from abeyance).

and (as particularly relevant here) “rescind the regulations and reconsider the regulatory determinations for PFHxS, PFNA, HFPO-DA ... and the Hazard Index mixture of these three plus PFBS to ensure that the determinations and any resulting drinking water regulation follow the legal process laid out in the Safe Drinking Water Act.” Press Release, EPA, EPA Announces It Will Keep Maximum Contaminant Levels for PFOA, PFOS (May 14, 2025), <https://perma.cc/5QHK-G5PA> (“PFAS Announcement”); *see* EPA Mot. at 8. EPA thereafter informed the Court that it intended “to file either a motion or letter with the Court clarifying [its] position in this litigation.” *See* Doc. No. 2128362 (Aug. 1, 2025).

On September 11, 2025, EPA filed its Motion for Partial Vacatur (Doc. No. 2134523), whereby the Agency seeks vacatur of (1) the Determinations to Regulate PFHxS, PFNA, and HFPO-DA on an individual basis; (2) the Determination to Regulate mixtures of two or more of the Index PFAS (i.e., PFHxS, PFNA, HFPO-DA, and PFBS); and (3) the Goals and Levels applicable to those PFAS and mixtures thereof. *See* EPA Mot. at 1, 22.

Water Associations support EPA’s motion and, for the reasons set forth by EPA as well as those Water Associations provide below, urge this Court to grant EPA’s motion for partial vacatur.

ARGUMENT

I. EPA correctly recognizes that it unlawfully proposed regulations for the Index PFAS before issuing Determinations to Regulate for those PFAS.

As explained above, *see supra* pp. 2-7, the Act mandates a multi-step and sequential process for regulating contaminants in drinking water. Here, EPA departed from that statutorily required regulatory process when it concurrently proposed Preliminary Determinations *and* regulations (i.e., Goals and Levels) for the Index PFAS, provided a single notice-and-comment period for both actions, and then concurrently issued Determinations to Regulate *and* regulations for the Index PFAS after that single comment period. In their opening brief, Water Associations explained, in detail, the legal flaws with EPA's approach and the problems with its justifications for the approach. *See* Doc. No. 2078734, at 18-32.

EPA now agrees, explaining that for the Index PFAS, the Agency “departed from the statutory scheme” and, by consequence, “denied the public and the regulated community the opportunity to adequately comment on and participate in the rulemaking process for the Index PFAS Goals and Standards with the benefit of the finalized regulatory determinations.” EPA Mot. at 2. The Agency explains its legal error, conceding that its reading of the Act at the time of the Rule “was in error and inconsistent with the ‘single, best meaning’ of the [Act] as informed by ‘all relevant interpretive tools.’” *Id.* at 10 (quoting *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024)); *see id.* at 10-16.

Water Associations will not duplicate EPA's analysis here and instead refer to the longer-form arguments provided in their opening brief. *See* Doc. No. 2078734, at 18-32. Water Associations, though, do note that courts have credited an agency's confession of error when considering whether to vacate the challenged agency action. *See* Resp'ts' Mot. for Partial Voluntary Remand at 7-8, *Safer Chems., Healthy Fams. v. EPA*, No. 17-72260 (consolidated) (Aug. 6, 2018) (explaining that promulgation of part of challenged rule violated the Administrative Procedure Act), *granted*, 791 F. App'x 653, 656 (9th Cir. 2019) (unpublished) ("[W]e conclude that [the agency's] request [for vacatur] is neither frivolous nor made in bad faith."); *Bldg. Indus. Legal Def. Found. v. Norton*, 231 F. Supp. 2d 100, 103, 108-09 (D.D.C. 2002) (observing that "[a]ll parties, *including the responsible agency*, agree that" the challenged actions "are substantively defective" and vacating the challenged actions (emphasis added)); *cf. Ethyl Corp. v. Browner*, 989 F.2d 522, 524 (D.C. Cir. 1993) (explaining that accepting an agency's confession of error and remanding the matter "to allow [the agency] to cure [its] own mistakes" is preferable to "wasting the courts' and the parties' resources").

II. EPA's error harmed Water Associations.

EPA has affirmatively withdrawn and waived its harmless-error defense. *See* EPA Mot. at 16-17; *cf. Freytag v. Comm'r*, 501 U.S. 868, 894 n.2 (1991) (Scalia, J., concurring) (defining "waiver" as the "intentional relinquishment or abandonment

of a known right or privilege” (citation omitted)). As the Agency correctly explains in its motion, harmless (or prejudicial) error is an affirmative defense that can be waived by an administrative agency. *See* EPA Mot. at 16-17 (collecting cases); *see also WildEarth Guardians v. U.S. Bureau of Land Mgmt.*, 870 F.3d 1222, 1239 (10th Cir. 2017) (finding that agency “forfeited any harmless error claim by failing to argue it before the district court”); *cf. Shinseki v. Sanders*, 556 U.S. 396, 406 (2009) (explaining the harmless-error doctrine embodied in the Administrative Procedure Act is “the same kind of ‘harmless-error’ rule that courts ordinarily apply in civil cases”). And where the government declines to argue for harmless error, “respect for the adversary process makes it inappropriate to address [harmless error] at all.” *United States v. Pryce*, 938 F.2d 1343, 1353 (D.C. Cir. 1991) (Silberman, J., dissenting) (alteration in original) (quoting *In re Barr Laboratories, Inc.*, 930 F.2d 72, 75-76 (D.C. Cir. 1991)).

Furthermore, the harmless-error doctrine has no application to the present situation, where the Agency, by its own admission, *see* EPA Mot. at 1-2, 10-16, entirely bypassed a notice-and-comment period required by statute. *See City of Waukesha v. EPA*, 320 F.3d 228, 246 (D.C. Cir. 2003) (per curiam) (explaining that “prejudice need not be shown ... ‘where the agency has entirely failed to comply with notice-and-comment requirements’” (quoting *Shell Oil Co v. EPA*, 950 F.2d 741, 752 (D.C. Cir. 1991) (per curiam))); *see also Chamber of Commerce of U.S. v.*

SEC, 443 F.3d 890, 904 (D.C. Cir. 2006) (agency’s “outright dodge” of procedural requirements may “permit a limited showing of prejudice”); *Sugar Cane Growers Coop. v. Veneman*, 289 F.3d 89, 96 (D.C. Cir. 2002) (“[A]n utter failure to comply with notice and comment cannot be considered harmless if there is any uncertainty at all as to the effect of that failure.”). It does not matter that EPA essentially (and impermissibly) combined two statutorily required notice-and-comment periods, thereby affording commenters a single but much more limited opportunity for comment. In *Mack Trucks, Inc. v. EPA*, this Court “strongly reject[ed]” the notion that an agency’s failure to allow for notice and comment on an interim rule was harmless because the agency was providing notice and comment for a pending final rule. 682 F.3d 87, 95 (D.C. Cir. 2012). “Were that true, agencies would have no use for the [Administrative Procedure Act] when promulgating interim rules.” *Id.* The same is true with regard to the sequential steps of the rulemaking process here.

In any case, EPA’s error prejudiced interested parties, including Water Associations. Demonstrating harmless error is not “a particularly onerous requirement,” *Jicarilla Apache Nation v. U.S. Dep’t of Interior*, 613 F.3d 1112, 1121 (D.C. Cir. 2010) (quoting *Shinseki*, 556 U.S. at 410), and application of the rule requires a “case-specific application of judgment,” *id.* (quoting *Shinseki*, 556 U.S. at 407). Importantly, the harmless-error rule does not require a party to show *actual* prejudice or, in the case of a challenge related to notice-and-comment procedures,

additional considerations it would have raised if given the opportunity. *See Waukesha*, 320 F.3d at 246; *Sprint Corp. v. FCC*, 315 F.3d 369, 377 (D.C. Cir. 2003); *Sugar Cane Growers*, 289 F.3d at 97.

To see how Water Associations (and other interested parties) were prejudiced, consider the timeline: In March 2023, EPA issued its combined Preliminary Determinations and proposed regulations for the Index PFAS. That single document was supported by occurrence data and modeling based on the UCMR 3 dataset, further supplemented by 23,130 results from state datasets. *See* 88 Fed. Reg. at 18,678. Water Associations were permitted opportunity to comment on *that* dataset, and they did so. Then, in April 2024, EPA issued the combined Final Determination and final regulations for the Index PFAS. “[B]ased on public comment,” that second document included an updated occurrence analysis that was based on the previous dataset *plus* “65,537 analytical results from 1,156 systems across 28 states.” 89 Fed. Reg. at 32,585, 32,598. It is undisputed that EPA did not provide a comment period for the expanded data upon which it relied.

Had the process unfolded as the Act requires—and how EPA now admits it should have unfolded—the Agency would first have published the Preliminary Determinations, interested parties (including Water Associations) would have commented and submitted data, EPA would have published its Final Determination and *proposed* regulations (including the final data on which EPA would principally

rely), and then interested parties would have been afforded a second opportunity to comment. That second comment period would have provided Water Associations an opportunity to provide their expert views on the interplay between (1) the vastly expanded occurrence data made available during the first comment period and (2) the cost-benefit analysis, i.e., the Health Risk Reduction and Cost Analysis required by 42 U.S.C. § 300g-1(b)(3)(C)(i), which is relevant to determining the Goal and Level for a particular contaminant. Instead, EPA afforded interested parties just one comment period, and the final regulations were therefore based on tens of thousands of analytical results on which neither Water Associations nor any interested party had opportunity to comment. *See Waukesha*, 320 F.3d at 246 (By not providing opportunity to comment, EPA cannot establish that all “possible objections” were “given sufficient consideration.” (citation omitted)).

Water Associations, in fact, raised these same concerns to EPA during the rulemaking process, urging the Agency to not move forward “without considering incoming data” that was “currently [being] collected” under UCMR 5 and then allowing interested parties to analyze and comment on that data. Comments of AWWA at 4, 12 (May 30, 2023), Doc. ID EPA-HQ-OW-2022-0114-1759, <https://www.regulations.gov/comment/EPA-HQ-OW-2022-0114-1759>; *see id.* at 2-3, 14-19, 22-23; *accord* Comments of AMWA at 8-9, 11 (May 30, 2023), Doc. ID EPA-HQ-OW-2022-0114-1738, <https://www.regulations.gov/comment/EPA-HQ->

OW-2022-0114-1738. AWWA explained that, with that data in hand, it would be possible to improve EPA's "occurrence" analysis, especially with respect to "occurrence for smaller systems." Comments of AWWA, *supra*, at 9-12, 45.

In short, Water Associations clearly explained why they thought the existing data was deficient and what additional data they thought EPA should consider, and then explained with specificity how their comments would be different and more robust were that data made available for comment. EPA, however, ignored the Water Associations' concerns, then unveiled the exact data that they wished to see after the one and only comment period was over. That approach was prejudicial under this Court's case law. *See Window Covering Mfrs. Ass'n v. CPSC*, 82 F.4th 1273, 1285 (D.C. Cir. 2023) (prejudice shown when, as here, petitioner "expressed several concerns about the [agency's] data that might have been further developed or amplified" if petitioner had been given all the data on which the agency ultimately relied; record reflected possibility that petitioner "had something useful to say" but was nonetheless prevented from commenting on "critical information relied upon by the agency" (citation omitted)); *Chamber*, 443 F.3d at 904 (prejudice shown when commenter "indicate[d] with reasonable specificity" how it would've responded to new data "if given the opportunity" (citation modified)); *Waukesha*, 320 F.3d at 246 (prejudice finding appropriate when, as here, "new round" of comment would

“provide the *first* opportunity for interested parties to offer comments” on the issue or data in question (citation omitted)).

III. The Court can and should vacate those portions of the Rule that EPA requests be vacated.

In appropriate circumstances, this Court has discretion to vacate agency action prior to the completion of merits briefing. This case constitutes an appropriate instance to do so. *See supra* p. 13; *see also* EPA Mot. at 20-22.

This Court has long recognized that “vacatur is the normal remedy for a procedural violation,” although remand without vacatur *may* be appropriate “based on the seriousness of the order’s deficiencies and the likely disruptive consequences of vacatur.” *Nat. Res. Def. Council v. Wheeler (NRDC)*, 955 F.3d 68, 85 (D.C. Cir. 2020) (internal quotation marks and citation omitted). Where an agency fails to provide adequate opportunity for notice and comment—here, a statutory requirement—the seriousness of the procedural deficiency is patent: “[T]he entire premise of notice-and-comment requirements is that an agency’s decisionmaking may be affected by concerns aired by interested parties through those procedures.” *Id.* Accordingly, “the court typically vacates rules when an agency ‘entirely fail[s]’ to provide notice and comment.” *Daimler Trucks N. Am. LLC v. EPA*, 737 F.3d 95, 103 (D.C. Cir. 2013) (quoting *Shell Oil Co.*, 950 F.2d at 752 (vacating EPA final rule where proposed rule failed to provide notice of adopted amendments)); *see also*, *e.g.*, *NRDC*, 955 F.3d at 85 (“[F]ailure to provide the required notice and to invite

public comment ... is a fundamental flaw that normally requires vacatur of the rule.” (quoting *Heartland Reg’l Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009))); *Standing Rock Sioux Tribe v. U.S. Army Corps of Eng’rs*, 985 F.3d 1032, 1052 (D.C. Cir. 2021) (“[A]n agency that bypassed required notice and comment rulemaking obviously could not ordinarily keep in place a regulation while it completed that fundamental procedural prerequisite.”).

Here, EPA now acknowledges that it failed to provide the multiple, sequential notice-and-comment periods required by the Act. *See* EPA Mot. at 1-2, 10, 16; *see also supra* Part I. The Agency’s legal error constitutes the type of serious deficiency that typically warrants vacatur. EPA’s error, moreover, prevented interested parties (including Water Associations) from being able to provide informed comments on the data and information that ultimately supported EPA’s action regarding the Index PFAS. *See supra* Part II. That casts serious, insurmountable “doubt” on “whether the agency chose correctly” with regard to the regulatory determinations and regulations for the Index PFAS. *See Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm’n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993) (noting that the “seriousness” of a rule’s “deficiencies” reflects “the extent of doubt whether the agency chose correctly”).

Vacatur is also warranted because the Agency cannot cure the serious procedural deficiencies with the Determinations to Regulate and regulations for the

Index PFAS without “essentially restart[ing] the regulatory process.” *see* EPA Mot. at 20. EPA, moreover, has indicated in its motion and public announcement that it has no intention of attempting to cure its error while also keeping the underlying actions in place. The Agency instead wishes to “rescind the regulations” and “reconsider the regulatory determinations”—effectively restarting the regulatory process from the beginning. *See* PFAS Announcement, *supra*; EPA Mot. at 8. And, as EPA explains, the Act’s anti-backsliding provision and this Court’s precedent in *Natural Resource Defense Council v. Regan* makes it difficult to revise regulations and impossible to withdraw a valid Determination to Regulate, respectively, without judicial intervention. *See* EPA Mot. at 20-21; *supra* pp. 6-7.

Additionally, vacatur is warranted because it would have no “disruptive consequences.” *See NRDC*, 955 F.3d at 85 (citation omitted); *Allied-Signal*, 988 F.2d at 150-51; *see also Am. Bankers Ass’n v. Nat’l Credit Union Admin.*, 934 F.3d 649, 674 (D.C. Cir. 2019) (“A strong showing of one [vacatur] factor may obviate the need to find a similar showing of the other.”). As EPA explains, vacatur of the Index PFAS actions would not disrupt regulatory requirements to which regulated parties are presently subject because the first compliance deadlines for those portions of the Rule are more than a year away. *See* EPA Mot. at 21-22.⁷ Likewise, vacatur would

⁷ This, of course, does not alleviate Water Associations’ concerns that continued delays in the resolution of this case prejudice their members, as explained in their recently filed motion on this docket. *See* Unopposed Motion of Petitioners American

not, as a practical matter, disrupt public health or environmental protections that are presently in effect.

That said, so long as the Index PFAS provisions of the Rule remain in place, regulated parties (namely, public water systems) will need to explore and potentially take steps, such as hiring consultants or contractors, entering into procurement contracts, or planning and financing facility upgrades, to achieve compliance, given the high-cost and time-intensive capital projects water systems may need to undertake. For some water systems, that could mean increased costs for ratepayers or disruptions to local governments' budgetary priorities. Accordingly, not vacating the agency actions related to Index PFAS while EPA reconsiders those actions could have disruptive consequences.

CONCLUSION

For the foregoing reasons, Water Associations respectfully request that the Court grant Respondents' Motion for Partial Vacatur (Doc. No. 2134523).

Water Works Association and Association of Metropolitan Water Agencies to Reconsider Clerk's Order of September 16, 2025 (Sept. 26, 2025), Doc. No. 2137231. Even assuming EPA's motion for partial vacatur is granted, Water Associations' members will still be subject to the portions of the Rule concerning PFOA and PFOS, and those members would benefit greatly from having resolution regarding their compliance obligations sooner rather than later.

Date: September 26, 2025

Respectfully submitted,

/s/ Corinne V. Snow

Corinne V. Snow
VINSON & ELKINS LLP
2200 Pennsylvania Avenue NW
Suite 500 West
Washington DC 20037
csnow@velaw.com
Phone: (202) 639-6622
Fax: (917) 879-8998

*Counsel for Petitioners American Water
Works Association and Association of
Metropolitan Water Agencies
(Case No. 24-1188)*

CERTIFICATE OF COMPLIANCE

1. This response complies with the word limit of Federal Rule of Appellate Procedure 27(d)(2) because it contains 5,059 words, excluding the parts exempted by Federal Rules of Appellate Procedure 32(f) and 27(d)(2).

2. This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6), because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

Date: September 26, 2025

/s/ Corinne V. Snow

Corinne V. Snow
VINSON & ELKINS LLP
2200 Pennsylvania Avenue NW
Suite 500 West
Washington DC 20037
csnow@velaw.com
Phone: (202) 639-6622
Fax: (917) 879-8998

*Counsel for Petitioners American Water
Works Association and Association of
Metropolitan Water Agencies
(Case No. 24-1188)*

CERTIFICATE OF SERVICE

Pursuant to Federal Rule of Appellate Procedure 25, I hereby certify that on September 26, 2025, I electronically filed the foregoing document with the Clerk of the Court for the U.S. Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system, and served copies of the foregoing via the Court's CM/ECF system on all ECF-registered counsel.

Date: September 26, 2025

/s/ Corinne V. Snow

Corinne V. Snow
VINSON & ELKINS LLP
2200 Pennsylvania Avenue NW
Suite 500 West
Washington DC 20037
csnow@velaw.com
Phone: (202) 639-6622
Fax: (917) 879-8998

*Counsel for Petitioners American Water
Works Association and Association of
Metropolitan Water Agencies
(Case No. 24-1188)*